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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,262

01/14/2004

Venkateswarlu Karicheti

MPI03-007P1RNOMNIM

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7590

11/03/2006

BANNER & WITCOFF

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WASHINGTON, DC 20001

EXAMINER

DESAI, ANAND U

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/757,262	Applicant(s) KARICHETI ET AL.	
	Examiner Anand U. Desai, Ph.D.	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2006 has been entered.

Specification

2. The disclosure is objected to because of the following informalities:
3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Suggest, Methods and compositions for treating urological disorders using carboxypeptidase z identified as 8263.
4. The related application section on page 1 should be updated to describe benefit of priority to U.S. Provisional Application Serial No. 60/491, 156, filed July 20, 2003. As discussed in paragraph 2 of the Office action mailed March 28, 2005, not all of the provisional applications upon which priority is claimed provide adequate support under 35 U.S.C. 112 for claims 1-5, 7, and 23 of this application. Upon review of the provisional applications it appears U.S.S.N 60/491,156, filed July 30, 2003 provides adequate support under 35 U.S.C. 112 for claims 1-5, and 23 of this application. Particular support for claims disclosing the use of the sequences identified as SEQ ID NOs: 103 & 104 was found on pages 43-47 of U.S. provisional application 60/491,156. The priority date is July 30, 2003.

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5. The abstract of the disclosure is objected to because the amended Abstract appears to describe 8263 transcripts. Suggest, identifying Carboxypeptidase Z as the transcript identified as 8263, such as, "The present invention relates to methods for diagnosis and treatment of urological disorder or urological disorders. Specifically, the present invention identifies the differential expression of Carboxypeptidase Z identified as 8263 gene transcripts in tissues relating to urological disorder, relative to their expression in normal, or non-urological disorder disease states, and/or in response to manipulations relevant to a urological disorder. The present invention describes methods for the diagnostic evaluation and prognosis of various urological diseases, and for the identification of subjects exhibiting a predisposition to such conditions. The invention also provides methods for identifying a compound capable of modulating a urological disorder or urological disorders. The present invention also provides methods for the identification and therapeutic use of compounds as treatments of urological disorders."

See MPEP § 608.01(b).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-5, 7, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In claim 1, it is unclear how "determining the effect" identifies a compound capable of treating urinary incontinence? No effect can be considered an effect when one administers the

compound in the animal model of urinary incontinence. It is unclear how no effect can identify a compound capable of treating urinary incontinence.

Suggest amending claim 1 to identify an effect on the animal model of urinary incontinence.

1. (Currently Amended) A method for identifying a compound capable of treating urinary incontinence, comprising:

a) combining a compound to be tested with a sample comprising a polypeptide selected from the group consisting of:

i) a polypeptide comprising the amino acid sequence of SEQ ID NO: 104; and

ii) a polypeptide encoded by the nucleotide sequence set forth in SEQ ID NO: 103;

under conditions suitable for binding of the compound to the polypeptide;

b) detecting binding of the compound to the polypeptide to thereby identify a compound which binds to the polypeptide; and

c) identifying a compound capable of reducing ~~determining the effect of the compound~~ on urinary incontinence in an animal model of urinary incontinence, thereby identifying a compound capable of treating urinary incontinence.

Claims dependent on claim 1 do not cure the deficiency of claim 1, and are rejected for depending on claim 1.

Conclusion

9. No claims are allowed.

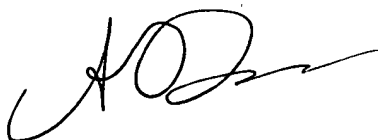
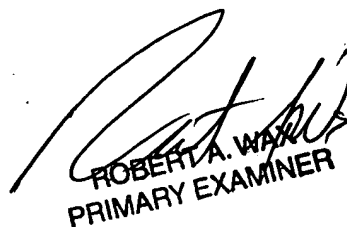
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

October 27, 2006

A handwritten signature in black ink, appearing to be 'A. D.', written in a cursive style.A handwritten signature in black ink, appearing to be 'Robert A. Wax', written in a cursive style. Below the signature is a rectangular stamp with the text 'ROBERT A. WAX' and 'PRIMARY EXAMINER' in a bold, sans-serif font.